HEARTFAID

D3 Report on Quality Assurance Process

Submission date: 15/06/2006
Due date of document: 30/04/2006

HEARTFAID

A KNOWLEDGE BASED PLATFORM OF SERVICES FOR SUPPORTING MEDICAL-CLINICAL MANAGEMENT OF THE HEART FAILURE WITHIN THE ELDERLY POPULATION

Project summary	
Project acronym:	HEARTFAID
Project identifier:	IST – 2005 – 027107
Duration of the Project:	01/02/2006 – 31/01/2009
Project Co-ordinator:	UNICAL University of Calabria (Italy)
Thematic Priority:	Information Society Technology
Instrument:	Specific Targeted Research or Innovation Project

Consortium

- UNICAL- Università della Calabria (Italy)
- UNICZ- Università degli studi Magna Graecia di Catanzaro (Italy)
- UNIMIB- Università degli studi di Milano Bicocca (Italy)
- JUMC- Jagiellonian University Medical College (Poland)
- VMWS- Virtual Medical World Solutions Ltd (United Kingdom)
- FORTHNET S. A.- Hellenic Telecommunications and Telematic Applications Company S. A. (Greece)
- SYNAP- Synapsis s.r.l. (Italy)
- CNR- Consiglio Nazionale delle Ricerche (Italy)
- FORTH-Foundation for Research and Technology Hellas (Greece)
- RBI- Rudjer Boskovic Institute (Croatia)
- AUXOL- Istituto Auxologico Italiano (Italy)

D3 Quality Assurance Process Report

Document summary	
Document title:	Quality Assurance Process Report
Document classification:	Deliverable D3
Dissemination level:	PU
Submission date:	15 June 2006
Due date:	30 April 2006
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Work package:	WP0 – Management
Report version:	1.1

Short description
This document contains the description of the process aimed to ensure the quality control of the deliverables of HEARTFAID project.

Change record		
Version number	Changes	Release date
1.0 1.1	First draft of the document Format and style changes	04/05/2006 20/05/2006

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Executive Summary

The aim of the quality assurance process is to ensure a high quality level of the HEARTFAID deliverables.
In order to achieve the aim of the quality assurance process, an internal review of the most critical deliverables will be performed, that is to say the most representative and significant deliverables to the overall results of the project. A list of the most critical deliverables is provided in Annex I.

Moreover, one or more revisers have been chosen for each deliverable in the aforementioned list according to the following criteria:

> *"for each deliverable the revisers are the partners who need the deliverable as input for their work."*

In this way the possibility of disputes among partners about the quality of the deliverables should be avoided.

In this document it is provided also a deep description of the procedures for the checking of the deliverables. These procedures will be performed via exchanges of Comments Review Sheets among the author of the deliverable and the revisers. All the documents produced during the checking procedures will have to be exchanged via the HEARTFAID web site. In Annex II we include the format templates for the deliverables and for the documents involved in the checking procedure.

All the actions performed during the quality control procedures will be registered by the Coordinator in the Quality Assurance Dossier. In this way the coordinator will be able to supervision the whole quality assurance process.

Moreover, at the end of this document, it is provided a list of conventions regarding the format of the documents and the file naming.

1 The Quality Assurance Process

The purpose of this document is to describe the quality procedures that will be adopted during the HEARTFAID project.

The mainly objective of the quality assurance process is to ensure the adhesion of the deliverables to the requirements described in the DoW. The above mentioned objective will be pursued in order to:

1. assure intermediate and final products with very high quality characteristics;
2. improve the management process of the project, in particular to avoid disputes among partners about the quality level of the deliverables.
3. satisfy the expectations of the EU Commission.

2 Subject of the controls

Only a subset of the whole list of deliverables will be checked via the procedures described in this report. The aforementioned subset will be chosen in order to include the most critical deliverables to the successful fulfilment of the project.

In this way it will be possible to focus the attention on the principal objectives of the project and to avoid exploiting too many resources in the control process.
Each WP leader will be responsible for the quality level of the deliverables produced in his work package not included in the Annex I list.

3 Actors of the quality assurance process

The responsibles for the implementation of the quality assurance process will be the Work Package Leaders Group (WPLG) and the Scientific and Technical Advisory Board (STAB).

In particular, for every deliverable included in the Annex I there will be one or more revisers among the components of the WPLG. The revisers will have the duty to check the quality level of the specified deliverables, following the procedures described in the fourth paragraph of this report.

The most critical deliverables (in respect of the correct execution of the project) will be controlled by the revisers of the WPLG and by one or more component of the STAB. The participation of external revisers will ensure a greater objectivity in the control of deliverables for which the maximum correctness is demanded.
The complete list of revisers for every deliverables is provided in the Annex I.

4 Quality control procedures

During HEARTFAID project two different kinds of deliverables will be produced: documental deliverables and system prototypes.
There will be different control procedures in order to better manage the different nature of the deliverables.

4.1 Documental deliverables control procedure

The control procedure for the documental deliverables aims to ensure the correctness and thoroughness of formal and content aspects of the documental deliverables. The control procedure will be carried out by the partner who will produce the deliverable ("the author") and by the revisers specified (for the deliverable) in Annex I.

The steps of control procedure are the following:

1. The author produces the draft of the deliverable and sends it to the revisers and to the coordinator (this action has to be recorded in the Quality Assurance Dossier).

2. The revisers perform a deep analysis of the document and compile a Review Comments Sheet (see Annex II), in which they explain where the deliverable should be changed and how to perform the improvements.

3. The revisers send the Review Comments Sheets to the author and to the coordinator (for the Quality Assurance Dossier).

4. After receiving the Review Comments Sheet, the author can:
   1. accept the requested changes and perform the necessary actions;
   2. express his disagreement to the review comments.

   In the last case the author and the revisers should come to an agreement on the changes to perform. The procedure should be handled with the minimum delay, in order to avoid any hindrance to the project. If the dispute among author and revisers does not reach a solution, the coordinator has the faculty to break the procedure and to decide the actions to be performed on the deliverable draft. Both author and revisers have to accept the coordinator decisions. The agreement on the changes or the coordinator decision has to be recorded in the Quality Assurance Dossier.

5. Once the previous matter is solved, the author should implement the "agreed" changes. The new version of the deliverable should be sent to the revisers and to the coordinator (this action has to be recorded in the Quality Assurance Dossier).

6. The revisers perform a second review of the document, in order to check if the corrective actions have been executed on the document:
   1. If the deliverable satisfies the quality requirements, the reviser advises the coordinator and the author (this decision has to be recorded in the Quality Assurance Dossier).
   2. If the corrective actions have not been implemented the process goes back to step 3.

7. When the final version of the document is reached, the author sends the deliverable to the coordinator, who will forward it to the Commission.

4.2 System prototypes control procedure

The objective of the system prototypes control procedure is to verify that the intermediate services and tools developed during the project have all the characteristics needed for their integration in the HEARTFAID platform.

Please note that the final prototype of the platform will not be tested via the procedures described in this report. The test of the final prototype will be carried out during the WP7, following the methodologies described in the DoW.
Instead, the procedures described in the present paragraph are aimed to check the functionalities of the components of HEARTFAID platform developed as *"intermediate"* system prototype, in order to ensure that the single parts of the platform are correctly implemented.

For the control of the system prototypes, the producer of the prototype ("the producer") will have to provide two documents:

1. A report where the description of the system prototype is provided; note that this report is requested also in the DoW, and should be structured as the other documental deliverables of the project.
2. A Test Description Report, where the producer describes the tests carried out in order to prove the functionalities of the prototype.

The first document should be checked via the procedure described in the paragraph 4.1.

The Test Description Report instead will be analyzed via the following steps:

1. The producer sends the Test Description Report (see Annex II) to the revisers and to the coordinator (this action has to be recorded in the Quality Assurance Dossier)..

2. The revisers list a set of comments and corrective actions in a Review Comments Sheet. In particular, the revisers can ask the producer to

perform more tests or to make some improvements on the system prototype. Then the reviser sends the Review Comments Sheet to the coordinator (for the Quality Assurance Dossier) and to the producer.

3. The producer have two options:
   1. to accept the comments and perform the requested actions;
   2. to reject the Review Comments Sheet and start a dealing with the revisers.

   In the second case the two parts should try to find an agreement. If they do not reach a common point of view, the coordinator can impose his decision The agreement on the comments or the coordinator decision has to be recorded in the Quality Assurance Dossier..

4. The producer should then implement the "agreed" corrections and forward the modified document to the revisers and to the coordinator (this action has to be recorded in the Quality Assurance Dossier).

5. The revisers perform a second review of the Test Description Report. At the end of this second review they can:
   - accept the document (this decision has to be recorded in the Quality Assurance Dossier);
   - prepare another Review Comments Sheet. In this case the revisers send the second Review Comments Sheet to the producer and the procedure go back to point 3.

6. When the revisers are satisfied, they advise the coordinator and the producer.

In order to manage emergency situations the coordinator can change or simplify the control procedures described in paragraphs 4.1 and 4.2.

5 Instruments

The QA process requires an intensive documents exchange. All the documents exchange for the QA process will be supported by the project web site. In particular the web site will have a restricted Download/Upload area where the partners only will be able to access and to exchange the files. Moreover, the website will support the document versioning.

If necessary, the exchange of the documents involved in the quality assurance process could be performed via email or other means.

6 Quality Assurance Dossier

In order to supervise in the best way the quality assurance process, the coordinator will keep and manage the Quality Assurance Dossier. The Quality Assurance Dossier will collect all the documents produced during the quality assurance process.
In particular, there will be the following sections:

1) Quality Assurance History:
In this section all the actions performed during the quality assurance process will be recorded. Which deliverables will be recorded, who will be the revisers, when the review will be performed.

2) Documental Deliverables Section:
In this section all the documental deliverables checked via the procedure described in the paragraph 4.1 will be filed.

3) Test Description Reports Section:
In this section all the Test Description Report provided for the system prototypes will be collected. Also the agreed actions among producer and revisers or the coordinator decisions have to be stored in this section.

4) Review Comments Sheets Section:
The Review Comments Sheets will be stored in this section. Also the agreed changes among author and revisers or the coordinator decisions have to be stored in this section.

7 Documents Templates

For the following reasons a standardization of documents templates is strongly suggested:

1. the same format for every document ensures a better comprehension and an immediate readability;
2. the file name standardization is very useful for the document versioning;
3. the same internal structure helps the information retrieval;

In order to adopt a common style for the principal documents, the following templates are included in the Annex II:

1. Project Deliverables;
2. Test Description Section;
3. Review Comments Section.

Moreover, all the documents produced during HEARTFAID should respect the following rules:

File type:
The draft versions of the files should be produced as Microsoft Word or PDF file. The final version of the documents should be provided only in PDF format, especially for the files which will be uploaded on the web site.

File name:
All the files should be named with the name of the project, the name of document and the version number. For example:

HEARTFAID_DocumentName_Draft#.#.pdf
HEARTFAID_DocumentName_Final.pdf

Page format:
The page margins should be 4 cm left and 3 cm for all other sides. The page size is A4.

Title numbering:
The title numbering follows the architecture of paragraphs, sub-paragraphs and sub-sub-paragraphs.

Styles:
All text must be in one column format. Text must be fully justified, in Times New Roman font, 12 points-size, single spaced interlines.

Annex I

Table 1. List of the most critical deliverables[1]

Deliverable Number	Deliverable Name	Deliverable Type	Revisers
D5	Medical-clinical processes and requirements in HF domain and formulation of the decision making problems	Documental Deliverable	1)STAB member: Goran Krstacic 2) RBI
D8	Definition and formulation of the organization and management models for the healthcare delivery	Documental Deliverable	FORTHNET
D9	Specifications of all biomedical data, signs and symptoms relevant to the HF	Documental Deliverable	1) STAB member: Mihai Gherghiade 2) CNR 3) RBI
D11	Functional Specification of the middleware	Documental Deliverable	VMWS
D14	Specification of Data acquisition and transmission infrastructure	Documental Deliverable	SYNAPSIS
D15	Functional specifications of Data preprocessing and Decision Support service	Documental Deliverable	UNIMIB
D19	Prototype of Data acquisition and transmission infrastructure	System Prototype	SYNAPSIS
D20	Clinical standards and first middleware prototype	System Prototype	UNICAL
D22	Ontologies and knowledge representation	Documental Deliverable	STAB Member: Nada Lavrac
D23	User needs analysis and functional specifications of the HEARTFAID platform service	Documental Deliverable	UNICZ
D28	Integration and Interoperability middleware	System Prototipe	FORTH
D29	Models and Methods for Knowledge Discovering	Documental Deliverable	STAB Member: Nada Lavrac
D31	Knowledge Discovering System	System Prototipe	RBI

[1] During the project the above list could be changed in order to satisfy the needs of the Quality Assurance Process.

Annex II

List of templates:

1) Deliverables template
   This template should be used by the author for the documental deliverables of the project.

2) Review Comments Sheets
   Reviser should use this template to advise the author of the deliverables about the changes that should be performed.

3) Test Description Report
   This template should be used by the producer of a system prototype in order to describe the tests performed on the system and the obtained results.